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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,602	12/12/2003	Hao-Jan Lin	JCLA10516	1741
23900	7590	01/29/2009	EXAMINER	
J C PATENTS, INC. 4 VENTURE, SUITE 250 IRVINE, CA 92618				NGUYEN, QUANG
ART UNIT		PAPER NUMBER		
1633				
MAIL DATE		DELIVERY MODE		
01/29/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,602	LIN ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 September 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

This application was transferred to Examiner Quang Nguyen, Ph.D. in AU 1633.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/30/08 has been entered.

Amended claims 1-14 are pending in the present application, and they are examined on the merits herein.

Response to Amendment

The rejection under 35 U.S.C. 112, first paragraph, for New Matter was withdrawn.

The rejection under 35 U.S.C. 103(a) as being unpatentable over Lin et al (US 6,436,709) in view of Tomalia (US2002/0013283) was withdrawn in light of Applicant's amendment.

Information Disclosure Statement

The information disclosure statement filed 1/14/09 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each

non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***This is a new ground of rejection necessitated by Applicant's amendment.***

In amended independent claims 1 and 11, while these claims recite "the sample solution comprises at least the biological material" and "the sample solution comprises at least a nucleic acid", respectively, they also recite "the biological material is delivered without using carriers", and therefore the later limitation renders the claims indefinite. This is because the biological material is already in a solution which is by definition is a homogenous mixture composed of two or more substances (e.g., a solute dissolved in a solvent); and therefore in such a solution at least one other substance (e.g., a solvent or water) can be considered to be a carrier for the other. Yet, the later negative limitation recites "without using carriers". It is further noted that the term "carriers" is not defined in the present application. Accordingly, the metes and

bounds of the claims are not clearly determined; and it is certain which prior art would meet all the limitation of the claims as written.

Additionally, claim 11 recites the limitation "**the biological material**" in lines 20-21 of the claim. There is insufficient antecedent basis for this limitation in the claim. This is because prior to this limitation, the term "biological material" was not recited in the claim. Instead, the phrase "a sample solution comprises at least a nucleic acid". Accordingly, the metes and bounds of the claims are not clearly determined.

Depending on how Applicants amend the instant claims, the following prior art made of record and is considered pertinent to applicant's disclosure:

1. Lin et al. (US 6,436,709; Cited previously) already disclosed a low pressure-accelerated particle gene gun having many similar features and properties of the gene gun used in the instant claimed methods except that the gene gun in US 6,436,709 has a material delivery system connected to the pressurized chamber rather than to the spray neck positioned between the diverging part and the converging part in a spray nozzle and to deliver micro-particles that are coated with nucleic acids into cytoplasma or nuclei of an animal or plant cell. However, US 6,436,709 teaches specifically that the spray tube in the gene gun is conical shape, allowing the speed of the gas flow to achieve the supersonic flow rate and the speed of the micro-particles to approach the speed of sound; and the spray nozzle comprises a contour entrance (a converging part, a neck and a diverging part), allowing the discharged micro-particles to

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be more evenly distributed and are not localized at the exit; and the gas pressure at the exit of the spray nozzle approaches atmospheric pressure.

2. Held et al. (WO 02/44391; IDS) already taught a method for introducing molecules such as nucleic acids, carbohydrates, peptides/proteins into cells and tissues using aerosol droplets (wet or dry) containing the molecules that are not associated with carrier particles, which are carried by a beam of gas to a nozzle through which the aerosol droplets are greatly accelerated to supersonic speed. Please note that the aerosol droplets containing the molecules fall within a broad scope of "a sample solution comprising at least a biological material", but they do contain at least solvents used to dissolve the molecules and/or an inert gas as carriers for delivery.

Conclusions

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN/
Primary Examiner, Art Unit 1633